Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Evaluation of the Effect of Preoperative Vitamin D on Postoperative Ionized Calcium Levels in Patients Undergoing Total Thyroidectomy

Protocol summary

Study aim

Investigate the effect of vitamin D injection before surgery on ionized calcium level and prevention of postoperative hypocalcemia in patients undergoing thyroid surgery.

Design

This study is a randomized, double-blind, parallel-group, controlled clinical trial conducted on 68 patients who are candidates for total thyroidectomy. Eligible patients will be randomly allocated into two groups: intervention (n = 34) and control (n = 34). Randomization will be performed through drawing method.

Settings and conduct

Study setting: surgery ward of Shahid Jalil Hospital in the city of Yasuj; Study population: Patients with thyroid diseases who will be candidates for total thyroidectomy surgery; Type of blinding: Double-blind; Method of blinding: In this study, both the patients and the outcome assessors will not be aware of the allocation of participants to the intervention and control groups, and the group allocation process will be performed randomly.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 18 and 70 years; Candidates requiring total thyroidectomy Exclusion criteria: Diagnosis of diabetes mellitus; Use of systemic corticosteroids for more than 7 days within the past three months; Presence of any underlying disease affecting parathyroid hormone, vitamin D, calcium, or albumin levels (e.g., chronic kidney disease); History of a major previous surgical procedure, such as total laryngectomy or parathyroidectomy; Preoperative hypocalcemia; Diagnosis of parathyroid adenoma.

Intervention groups

Intervention group (n=34): single intramuscular vitamin D injection (15 mcg / 600 IU) two weeks before surgery. Control group (n=34): no vitamin D injection.

Main outcome variables

Ionized calcium level ; Vitamin D level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251118068041N1**
Registration date: **2026-02-16, 1404/11/27**
Registration timing: **prospective**

Last update: **2026-02-16, 1404/11/27**
Update count: **0**

Registration date

2026-02-16, 1404/11/27

Registrant information

Name
Maryam Jamshidi
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-02-20, 1404/12/01

Expected recruitment end date

2027-02-20, 1405/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the Effect of Preoperative Vitamin D on Postoperative Ionized Calcium Levels in Patients Undergoing Total Thyroidectomy

Public title
Effect of vitamin D in Thyroidectomy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 18 and 70 years Candidates requiring total thyroidectomy
Exclusion criteria:
Diagnosis of diabetes mellitus Use of systemic corticosteroids for more than 7 days within the past three months Pregnancy History of ischemic heart disease Presence of any underlying disease affecting parathyroid hormone, vitamin D, calcium, or albumin levels (e.g., chronic kidney disease) History of a major previous surgical procedure, such as total laryngectomy or parathyroidectomy Substance abuse / drug addiction Preoperative hypocalcemia Change in the type of surgical procedurePatients with intraoperative parathyroid injury, including cases where the surgeon reports injury, autotransplantation of parathyroid tissue, or evidence of parathyroid ischemia Diagnosis of parathyroid adenoma before, during, or after surgery
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
0
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **68**
Randomization (investigator's opinion)
Randomized
Randomization description
Each participant will be assigned a unique number. Then, by simple random draw, participants will be allocated to each group using simple random sampling, with the total sample equally divided into the control group (n=34) and the intervention group (n=34).
Blinding (investigator's opinion)
Double blinded
Blinding description
Type of blinding: Double-blind; Method of blinding: In this study, both patients and outcome assessors will be unaware of the intervention received by each participant; to maintain blinding, the vitamin D injections in the intervention group and no injection in the control group will be managed so that outcome assessors will not be aware of the differences, and the appearance of the injection process will be kept similar for both groups.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Yasuj University of Medical Sciences
Street address
Shahid Motahari Blvd., Yasuj
City
Yasuj
Province
Kohgilouyeh-va-Boyrahmad
Postal code
75918-74831
Approval date
2024-05-08, 1403/02/19
Ethics committee reference number
IR.YUMS.REC.1403.021

Health conditions studied

1

Description of health condition studied
Patients with thyroid disorders who are candidates for total thyroidectomy
ICD-10 code
E83.51
ICD-10 code description
Hypocalcemia

Primary outcomes

1

Description
Ionized calcium level after surgery
Timepoint
Every 12 hours for 2 days postoperatively (4 measurements)
Method of measurement
Ionized calcium will be measured using standard laboratory biochemical assays.

Secondary outcomes

1

Description
Hypocalcemia-related complications
Timepoint
Continuously monitored for 2 days postoperatively
Method of measurement

Assessed by clinical evaluation and patient monitoring

2

Description
Requirement for additional calcium supplementation
Timepoint
During the 2-day postoperative period
Method of measurement
Recorded from patient treatment logs

3

Description
Vitamin D levels
Timepoint
Measured at baseline and before surgery
Method of measurement
Measured using standard laboratory biochemical assays

Intervention groups

1

Description
Intervention group: In this group, patients will receive a single intramuscular injection of vitamin D3 at a dose of 15 micrograms (600 IU), purchased from Darou Pakhsh Pharmaceutical Company, two weeks before undergoing total thyroidectomy. Each patient will receive one injection.
Category
Treatment - Drugs

2

Description
Control group: In this group, patients will not receive any injection two weeks before surgery and will receive routine hospital care. No additional drugs or supplementary interventions will be provided.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Jalil Hospital
Full name of responsible person
Maryam Jamshidi
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Gharani Blvd, Yasuj
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yasouj University of Medical Sciences
Full name of responsible person
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Yasuj University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Yasouj University of Medical Sciences
Full name of responsible person
Mohammad Bagher Jahantab
Position
Assistant Professor
Latest degree
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Not applicable

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Not applicable

Analytic Code
Not applicable

Data Dictionary
Not applicable